K021138

FEB 1 2 2003

Summary of Safety and Effectiveness

Date of Preparation: April 4, 2002

Submitter: Erich Jaeger GmbH
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Germany

Contact: Brian Long
SensorMedics Corp.
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Device Trade Name: SleepScreen/ApnoeScreen Cardio

Device Common/Classification Name: The SleepScreen/ApnoeScreen Cardio is an Erich Jaeger GmbH device classified under 73MBZ, "Ventilatory Effort Recorder, per Regulation No. 868.2375.

Predicate Device: ApnoeScreen Pro (K000396)

Intended Use:

The SleepScreen and ApnoeScreen Cardio are portable physiological signal recording devices intended to be used for testing patients suspected of having sleep-related breathing disorders. They are intended to be used under the direction of a physician. The devices may be used in the home, clinic, doctor's office or hospital.

The SleepScreen and ApnoeScreen Cardio, or any of the accessories supplied with it, are not to be used, alone or in combination, as an apnea monitor or as a component in an apnea monitoring system.

The SleepScreen and ApnoeScreen Cardio, or any of the accessories supplied with it, are not to be used, alone or in combination, as a life support device, a life support system, or as a critical component in a life support device or life support system.

Device Description:

The ApnoeScreen Cardio is the ApnoeScreen Pro (K000396) with the addition of two AC channels. The additional AC channels may be used to record electro-oculargram (EOG), electromyogram (EMG), electroencephalogram (EEG) and/or electrocardiogram (ECG).

The SleepScreen is the ApnoeScreen Pro (K000396) with the addition of eight AC channels. The additional AC channels may be used to record electro-oculargram (EOG), electromyogram (EMG), electroencephalogram (EEG) and/or electrocardiogram (ECG).

Comparison to Predicate Device:

The SleepScreen/ApnoeScreen Cardio is not significantly different from the predicate device, ApnoeScreen Pro (K000396). Simply, eight AC channels are now available for the SleepScreen and only two of the eight channels are available for the ApnoeScreen Cardio.

Summary of Performance Testing:

Performance testing was conducted in the laboratory to confirm compliance to device specifications; all functions were verified to operate as designed and intended, and measured parameters met required ranges and accuracies. Testing to internationally accepted standards for electrical safety and electro-magnetic compatibility were performed; the SleepScreen/ApnoeScreen Cardio complied with the requirements of these standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 2 2003

Erich Jaeger GmbH
C/O Mr. Brian Long
SensorMedics Corporation
22705 Savi Ranch Parkway
Yorba Linda, California 92887-4645

Re: K021138
Trade/Device Name: SleepScreen and ApnoeScreen Cardio
Regulation Number: 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: December 23, 2002
Received: December 24, 2002

Dear Mr. Long:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER: K021138

DEVICE NAME: SleepScreen and ApnoeScreen Cardio

INDICATIONS FOR USE:

The SleepScreen and ApnoeScreen Cardio are non-life-supporting portable physiological signal recording devices intended to be used for testing patients 7 years and older suspected of having sleep-related breathing disorders. The SleepScreen and ApnoeScreen Cardio are intended to measure and record oxygen saturation, pulse rate, body position, snoring, respiratory airflow, respiratory effort, PLM, EEG, EMG, EOG and ECG data. The devices may be used in the home, clinic, doctor's office or hospital.

The SleepScreen and ApnoeScreen Cardio are not intended for use as an apnea monitor or as a component in an apnea monitoring system. Additionally, the SleepScreen and ApnoeScreen Cardio are not intended to be used alone or in combination with another product as a life support device, a life support system, or as a critical component to a life support device or system. There is no claim of compatibility with diagnostic imaging equipment.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The Counter Use _____ (Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K021138